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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/729,432

12/04/2003

Ivan Sepetka

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EXAMINER

SEVERSON, RYAN J

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

11/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/729,432	Applicant(s) SEPETKA ET AL.	
	Examiner Ryan Severson	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-41, 43 and 44 is/are pending in the application.
- 4a) Of the above claim(s) 27-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-41, 43 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02 September 2008 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 38, 39 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Lau et al. (5,344,426).** Lau reference discloses a device having a cover (14) capable of covering the neck of an aneurysm and a delivery catheter with an expandable element (12) and a sheath (27, see figures 16-18). The sheath is folded over itself and is peeled back to release the cover. The catheter has a longitudinal axis and the cover is disposed about the expandable element (see figures 16-18). The catheter has a single lumen capable of receiving a guidewire (20). The cover of Lau reference is a metallic frame (see column 6, lines 31-33).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lau et al. (5,344,426) in view of Fogarty et al. (6,110,198).** Lau reference does not disclose an adhesive on the outer surface of the cover (stent). Attention is drawn to Fogarty reference, which teaches it is known to use an adhesive to secure a graft to a stent (see column 9, lines 13-15) to prevent the stent from migrating downstream relative to the graft. Further, the use of a graft with a stent is known in the art for a multitude of reasons, for example preventing restenosis or excessive cellular ingrowth through the openings in the stent. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the adhesive and graft of Fogarty reference with the stent of Lau reference to allow a graft to be placed securely on the stent.

6. **Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lau et al. (5,344,426) in view of Summers et al. (5,772,668).** Lau reference does not disclose an impermeable portion on the cover. Attention is drawn to Summers reference, which teaches it is known to include an impermeable portion on a frame (see column 3, lines 26-31 and 62-65) to be used at an aneurysm site to seal the aneurysm from further blood flow (see column 5, lines 58-61) to prevent the aneurysm from

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bursting. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the impermeable membrane of Summers reference on the stent of Lau reference to seal the aneurysm from further blood flow.

7. **Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lau et al. (5,344,426) in view of Hull (5,192,297).** Lau reference does not disclose the sheath is made from PTFE. Attention is drawn to Hull reference, which teaches it is known in the art to make sheaths of PTFE (see column 2, lines 62-64) to provide a sheath that is durable yet flexible. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the sheath of Lau reference of PTFE, as taught by Hull, to provide a sheath that is durable yet flexible.

Response to Arguments

8. Applicant's arguments filed 02 September 2008 have been fully considered but they are not persuasive. As an initial matter, Examiner notes that the arguments filed with the Request for Continued Examiner are the same as the arguments filed after-final on 22 July 2008. Therefore, the same response set forth in the advisory action mailed 22 August 2008 is set forth below.

9. Applicant argues Lau does not disclose "a cover for covering a neck of an aneurysm." However, cover 14 of Lau has been identified as the cover, thus meeting the limitations of the claims. The claims do not require any specific structure for the cover, and the limitation "for covering a neck of an aneurysm" is merely a functional limitation, and the cover of Lau is capable of being placed at the neck of an aneurysm to cover it.

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10. Applicant argues Lau does not disclose a sheath folded over itself at the distal end of the sheath, but instead discloses the fold at the proximal end of the sheath. In one interpretation, the fold is at a distal end of the catheter, thus meeting the limitations of the claims because the claims do not require the fold to be at the distal end "of the sheath" but merely to be "at a distal end." Alternatively, the left hand side of the sheath in figures 16-18 of Lau can be interpreted as the distal end because the terms proximal and distal are terms of orientation, also meeting the limitations of the claims.

11. Applicant argues the Lau system requires pushing of the guidewire and the pushing "may" be less desirable and "may" tend to buckle when pushed. However, there is no support for this assertion in the specification of the Lau patent and therefore the argument appears to merely be conjecture on the part of the applicant. The claims require the sheath be pulled back and this limitation is met by pulling the sheath as shown in the progression of figures 16-18. There are no claim limitations drawn to pushing or pulling of a guidewire or drawn to the manner in which the sheath is pulled back, and therefore arguments to that effect are not persuasive.

Conclusion

12. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued

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examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

13. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Severson whose telephone number is (571)272-3142. The examiner can normally be reached on Monday - Friday 8:30-5:00.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. S./
Examiner, Art Unit 3731

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731